

RECEIVED

JAN 22 2003

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

FORM PTO-1449

Attorney Docket No.:
25.01

TECH CENTER 1500/2000

09/992,957

Applicant: **Hans Herweijer, et al.**

Group:

Examiner:

U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

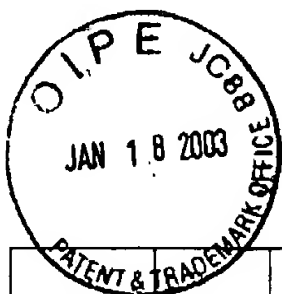
		Document Number	Publ. Date	Country or Patent Office	Class	Sub Class	Transl. Yes	No

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

DS		Svoboda et al., "RNAi in mouse oocytes and preimplantation embryos: effectiveness of hairpin dsRNA," Biochemical and Biophysical Research Communication; 2001, vol. 287, pp. 1099-1104
		Trubetskoy et al., "quantitative assessment of DNA condensation," Analytical Biochemistry; 1999, vol. 267, pp. 309-313
		Suter et al., "BAC-VAC, a novel generation of (DNA) vaccines: A bacterial artificial chromosome (BAC) containing a replication-competent, packaging -defective virus genome induces protective immunity against herpes simplex virus 1," PNAS; 1999, vol. 96 no. 22, pp. 12697-12702
		Trubetskoy et al., "Layer-by-layer deposition of oppositely charged polyelectrolytes on the surface of condensed DNA particles," Nucleic Acids Research; 1999, vol. 27, no. 15, pp. 3090-3095
		Trubetskoy et al., "Self-assembly of DNA-polymer complexes using template polymerization," Nucleic Acids Research; 1998, vol. 26, no. 18, pp. 4178-4185
		Trubetskoy et al., "Caged DNA does not aggregate in high ionic strength solutions," Bioconjugate Chem; 1999, vol. 10, pp. 624-628
		Krieg et al., "The role of CpG dinucleotides in DNA vaccines," Trends in Microbiology; 1998, vol. 6, no. 1, pp. 23-7
PS		Lipford et al., "Bacterial DNA as immune cell activator," Trends in Microbiology; 1998,

Buller

3/18/04



RECEIVED

JAN 22 2003

TECH CENTER 1600/2900

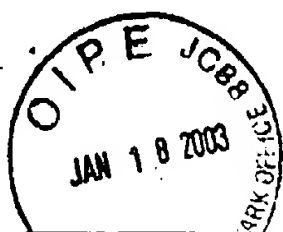
	vol. 6, no. 12, pp 496-500
88	Akbari et al., "DNA vaccination: transfection and activation of dendritic cells as key events for immunity," The Rockefeller University Press; 1999, vol. 189, no. 1, pp. 169-177
	Iwasaki et al., "Enhanced CTL responses mediated by plasmid DNA immunogens encoding costimulatory molecules and cytokines," The Journal of Immunology; 1997, vol. 158, pp. 4591-4601
	Etchart et al., "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," Journal of General Virology; 1997, vol. 78, pp. 1577-1580
	Herrmann et al., "Immune responses and protection obtained by oral immunization with rotavirus VP4 and VP7 vaccines encapsulated in microparticles," Virology; 1999, vol. 259, pp. 148-153
	Kaneko et al., "Oral DNA vaccination promoted mucosal and systemic immune responses to HIV envelope glycoprotein," Virology; 2000, vol. 267, pp. 8-16
	Chen et al., "Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles," Journal of Virology; 1998, pp. 5757-5761
	Gregoriadis et al., "Liposome-mediated DNA vaccination," REBS Letters; 1997, vol. 402, pp. 107-110
	MacGregor et al., "First Human Trial of a DNA-Based Vaccine for Treatment of Human Immunodeficiency Virus Type 1 Infection: Safety and Host Response," The Journal of Infectious Diseases; 1998, vol. 178, pp. 92-100
	Donnelly et al., "DNA Vaccines," Life Sciences; 1997, vol. 60, no. 3, pp. 163-172
	Tomasi "Introduction: an overview of the mucosal system," Handbook of Mucosal Immunology
	Fasano "Novel approaches for oral delivery of macromolecules," Journal of Pharmaceutical Sciences; 1998, vol. 87, no. 11
	Jackson et al., "Preparation and properties of totally synthetic immunogens," Vaccine; 2000, vol. 18, pp. 355-361
	DeNoon et al., "Conference coverage (ECP) combination vaccines): CEO: Biotech Breakthrough could shake vaccine industry," Aidsweekly Plus; 1998
	DeNoon "Conference coverage (ECP! Combination vaccines) 2202 vaccine market: \$7 billion," newsrx.com; 1998
	Irache et al., "Bioadhesion of lectin-latex conjugates to rat intestinal mucosa," Pharmaceutical Research; 1996, vol. 13, no. 11
	Shefner et al., "A novel class of anti-DNA antibodies identified in BALB/c mice," The Rockefeller University Press; 1991, vol. 173, pp. 287-296
	Eilat et al., "Monoclonal antibodies to DNA and RNA from NZB/NZW F1 mice: antigenic specificities and NH2 terminal amino acid sequences," The Journal of Immunology; 1984, vol. 133, no. 1
	Katsumi et al., "Humoral and cellular immunity to an encoded protein induced by direct DNA injection," Human Gene Therapy; 1994, vol. 5, pp. 1335-1339
88	Gilkeson et al., "Specificity of anti-DNA antibodies induced in normal mice by immunization with bacterial DNA," Clinical Immunology and Immunopathology; 1991, vol. 59, pp. 288-300

[Signature] 3/18/04



	Whiteside et al., "Clinical usefulness of the crithidia luciliae test for antibodies to native DNA," Anti-DS DNA in Disease; vol. 72, no. 5
	Tron et al., "Relationships between antibodies to native DNA and glomerulonephritis in systemic lupus erythematosus," Clin. Exp. Immunol; 1977, vol. 28, pp.426-432
	Nakamura et al., "Microhemagglutination test for detection of antibodies to nuclear sm and ribonucleoprotein antigens in systemic lupus erythematosus and related diseases," Detection of sm and RNP antibodies; 1978, vol. 70, no. 5
	Wolff et al., "Long-term persistence of lasmid DNA and foreign gene expression in mouse muscle," Human Molecular Genetics; 1992, vol. 1, no. 6, pp. 363-369
	Liebert et al., "What about those monkeys that got T-Cell lymphoma," Human gene Therapy; 1993, vol. 4, pp. 1-2
	Liebert et al., "Safety issues related to retroviral-mediated gene transfer in humans," Human Gene Therapy; 1991, vol. 2, pp. 5-14
	Lahijani et al., "Quantitation of host cellDNA contaminate in pharmaceutical-grade plasmid DNA using competitive polymerase chain reaction and enzyme-linked immunosorbent assay," Human Gene Therapy; 1998, vol. 9, pp. 1173-1180
	Lahijani et al., "High-yield production of pBR322-derived plasmids intended for human gene therapy by employing a temperature-controllable point mutation," Human Gene Therapy; 1996, vol. 7, pp. 1971-1980
	Boyle "Disease and fertility control in wildlife and feral animal populations: options for vaccine delivery using vectors," Tereprod. Fertil. Dev.; 1994, vol. 6, pp. 393-400
	Sato et al., "Immunostimulatory DNA sequences necessary for effective intradermal gene immunization," Science; 1996, vol. 273
	Roman et al., "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants," Nature Medicine; 1997, vol. 3, no. 8
	Leclerc et al., "The preferential induction of a TH1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA," Cellular Immunology; 1997, vol. 179, pp. 97-106
	Fu et al., "Priming of cytotoxic T lymphocytes by DNA vaccines: requirement for professional antigen presenting cells and evidence for antigen transfer from myocytes," Molecular Medicine; 1997, vol. 3, no. 6, pp. 362-371
	Kim et al., "Engineering of in vivo immune responses to DNA immunization via codelivery of costimulatory molecule genes," Nature Biotechnology; 1997, vol. 15, pp. 641-646
	Chow et al., "Development of TH1 and Th2 populations and the nature of immune responses to hepatitis B virus DNA vaccines can be modulated by codelivery of various cytokine genes," The Journal of Immunology; pp.1320-1329
	Xiang et al., "Manipulation of the immune response to a plasmid-encoded viral antigen by coinoculation with plasmids expressing cytokines," Immunity; 1995, vol. 2, pp. 129-135
	Pardoll et al., "Exposing the immunology of naked DNA vaccines," Immunity; 1995, vol. 3, pp. 165-169
	Quong et al., "DNA protection form extracapsular nucleases, within chitosan- or poly-l-lysine-coated alginate beads,"
DS	Roy et al., "oral gene delivery with chitosan-DNA nanoparticles generates immunologic protection in a murine model of peanut allergy," Nature Medicine; 1999, vol. 5, no. 4, pp. 387-391

DS 3/18/04



PS	Alapar et al., "Potential of particulate carriers for the mucosal delivery of DNA vaccines," Biochemical Society Transactions; 1997, vol. 25, p. 337S
	Jones et al., "Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration," Vaccine, 1997, vol. 15, no. 8, pp. 814-817
	Ermak et al., "Uptake and transport of copolymer biodegradable microspheres by rabbit peyer's patch M cells," Cell Tissue Res; 1995, vol. 279, pp. 433-436
	Florence et al., "Factors affecting the oral uptake and translocation of polystyrene nanoparticles: histological and analytical evidence," Journal of Drug Targeting; 1995, vol. 3, pp. 65-70
	Bockman et al., "Pinocytosis by epithelium associated with lymphoid follicles in the bursa of fabricius, appendix, and peyer's patches. An electron microscope study," Am. J. Anat.; vol. 136, pp. 455-478
	Mathiowitz et al., "Biologically erodable microspheres as potential oral drug delivery systems," Nature; 1997, vol. 386
	Ishii et al., "cationic liposomes are a strong adjuvant for a DNA vaccine of human immunodeficiency virus type 1," Aids Research and Human Retroviruses; 1997, vol. 13, no. 16, pp. 1421-1428
	Jiao et al., "Direct gene transfer into nonhuman primate myofibers in vivo," Human Gene Therapy; 1992, vol. 3, pp. 21-33
	Wang et al., "Induction of antigen-specific cytotoxic T lymphocytes in a humans by a malaria DNA vaccine," Science; 1998, vol. 282, pp. 476-480
	Ulmer et al., "Heterologous protection against influenza by injection of DNA encoding a viral protein," Science; 1993, vol. 259, pp. 745-749
	Acsadi et al., "Direct gene transfer and expression into rat heart in vivo," The New Biologist; 1991, vol. 3, no. 1, pp. 71-81
	Tang et al., "Genetic immunization is a simple method for eliciting an immune response," Nature; 1992, vol. 356, pp. 152-154
	Wolff et al., "Direct gene transfer into mouse muscle in vivo," Science; 1990, vol. 247, pp. 1465-1468
	Ulmer et al., "Generation of MHC class I-restricted cytotoxic T lymphocytes by expression of a viral protein in muscle cells: antigen presentation by non-muscle cells," Immunology; 1996, vol. 89, pp. 59-67
	Donnelly et al., "DNA vaccines," Annu. Rev. Immunol.; 1997, vol. 15, pp. 617-648
PS	Suhrbier "Multi-epitope DNA vaccines," Immunology and Cell Biology; 1997, vol. 75, pp. 402-408

Examiner: Initial citation considered. Draw line through citation if not in conformance and not Considered. Include copy of this form with next Action to applicant

[Signature] 3/18/04